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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,198	01/06/2006	Jukka Salonen	0933-0247PUS1	1824
2292	7590	01/15/2008	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			SALMON, KATHERINE D	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747			1634	
			NOTIFICATION DATE	DELIVERY MODE
			01/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[mailroom@bskb.com](mailto:mailroom@bskb.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/538,198	SALONEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED, (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-23 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 8-9, 13-15, drawn to a method of determining whether a subject will benefit from treatment with a drug affecting the noradrenaline sensitivity or sympathetic activity of the subject. This Group is subject to further restriction as discussed below.

Group II, claim(s) 10, drawn to a method of determining whether a subject will be at increased risk of adverse effects if subtype-nonselective α<sub>2</sub>-agonists, a diuretic, or a calcium channel blocker are administered. This Group is subject to further restriction as discussed below.

Group III, claim(s) 11-15, drawn to a method of selecting a subject for clinical trials testing the antihypertensive effects of compounds. This Group is subject to further restriction as discussed below.

Group IV, claim(s) 17-18 and 21, drawn to a method of targeting treatment of hypertension in a hypertensive subject by determining the pattern or alleles and treating with a drug modulating, inhibiting or activating the vascular alpha or beta adrenergic receptors. This Group is subject to further restriction as discussed below.

Group V, claim(s) 19-20, drawn to a method of targeting treatment of hypertension in a hypertensive subject by determining the pattern or alleles and treating with a drug which is an ACE inhibitor, angiogenesis II inhibitor, or angiogenesis receptor inhibitor. This Group is subject to further restriction as discussed below.

Group VI, claim(s) 22, drawn to a kit comprising means for determining the pattern of alleles and optionally software.

2. Claims 1-7, 23 links Groups I, II, and III. The requirement among the linked inventions is subject to the nonallowance of the linking claims, Claims 1-7, 23. Upon the allowance of the linking claims, the requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

2. Claims 16, 23 links Groups IV and V. The requirement among the linked inventions is subject to the nonallowance of the linking claims, Claims 16, 23. Upon the allowance of the linking claims, the requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

**Further Restriction Requirement:**

3. Additionally Group I is subject to further restriction. Applicant must elect a specific drug modulating compound from the group of ACE inhibitor, angiogenesis II inhibitor, angiogenesis receptor inhibitor,  $\alpha$ 2b-selective, or  $\alpha$ 2b-nonspecific.

Additionally Group II is subject to further restriction. Applicant must elect a specific compound from the group of subtype-nonspecific  $\alpha$ 2-agonists, a diuretic, or a calcium channel blocker.

Additionally Group III is subject to further restriction. Applicant must elect a specific drug modulating compound from the group of ACE inhibitor, angiogenesis II inhibitor, angiogenesis receptor inhibitor,  $\alpha$ 2b-selective, or  $\alpha$ 2b-nonspecific.

Additionally Group IV is subject to further restriction. Applicant must elect a specific drug modulating compound from the group of pindolol, propranolol, sotalol, timolol, acebutolol, atenolol, betaxolol, bisoprolol, esmolol, meteprolol, seliprolol, carvedilol, labetalol, clonidine, moxonidine, prazosin, or indapamid.

Additionally Group V is subject to further restriction. Applicant must elect a specific drug modulating compound from the group of captopril, cinapril, enalapril, imidapril, lisinopril, moexipril, perindopril, ramipril, trandolapril, candesartan, eprosartan, irbesartan, losartan, valsartan, or telmisartan.

The compounds listed in the above groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the

description fails to disclose that all of the compounds share a common property or activity. Each compound is a structurally distinct drug modulating compound with distinct effects and modes of operation.

4. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-VI, is detection of the D/D genotype of the human  $\alpha$ 2B-adrenoceptor. Groups I-VI do not share a special technical feature over the art because Heinonen et al. (The Journal of Clinical Endocrinology and Metabolism 1999 Vol 84 p. 2429)). Therefore Heinonen et al. teaches all the limitations of the technical feature and the technical feature fails to make a contribution over the prior art; therefore there is no special technical feature between Groups I-VI.

5. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571)

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272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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RAM R. SHUKLA, PH.D.  
SUPERVISORY PATENT EXAMINER